



Health Research Authority

North West - Preston Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

28 January 2019 (**Updated 04.02.2019**)

Dr Rebecca Foster
Research Fellow
Macmillan Survivorship Research Group
Health Sciences
University of Southampton
SO17 1BJ

Dear Dr Foster

Study title: HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer
REC reference: 16/NW/0425
Protocol number: RHM CAN1199
Amendment number: 9
Amendment date: 21 January 2019
IRAS project ID: 202342

- The amendment proposes changes to the protocol and supporting documents and also, changes to reflect the introduction of the General Data Protection Regulations.

Thank you for submitting the above amendment, which was received on 23 January 2019. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 18th January 2019 refers).

The modified amendment was by the Sub-Committee in correspondence. A list of the members who took part in the review is attached.

Ethical opinion

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [HORIZONS Recruitment Update Flyer for Waiting Room - Tracked]	1.0	09 January 2019

Copies of advertisement materials for research participants [HORIZONS Recruitment Update Flyer for Waiting Room]	1.0	09 January 2019
Covering letter on headed paper [HORIZONS 202342 REC 16 NW 0425 SA9 modified cover letter]		23 January 2019
Letters of invitation to participant [HORIZONS Qualitative Patient Invitation Letter - Tracked]	1.1	18 January 2019
Letters of invitation to participant [HORIZONS Qualitative Patient Invitation Letter]	1.1	18 January 2019
Letters of invitation to participant [HORIZONS Qualitative Second Patient Invitation Letter]	1.0	09 January 2019
Notice of Modified Amendment [Modified Substantial Amendment Form]	9	21 January 2019
Other [HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter - Tracked]	3.0	16 October 2018
Other [HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter]	3.0	16 October 2018
Other [HORIZONS 3-12 Month Post Treatment Questionnaire Reminder Letter - Tracked]	3.0	16 October 2018
Other [HORIZONS 3-12 Month Post Treatment Questionnaire Reminder Letter]	3.0	16 October 2018
Other [HORIZONS Baseline Reminder Letter - Tracked]	2.0	20 August 2018
Other [HORIZONS Baseline Reminder Letter]	2.0	20 August 2018
Other [HORIZONS Data Protection Statement]	1.0	30 November 2018
Other [HORIZONS Flyer for Online Completion of Questionnaires - Tracked]	2.0	16 October 2018
Other [HORIZONS Flyer for Online Completion of Questionnaires]	2.0	16 October 2018
Other [HORIZONS Follow up online questionnaire letter no email]	1.0	16 October 2018
Other [HORIZONS Follow up Online Questionnaire Letter - Tracked]	3.0	16 October 2018
Other [HORIZONS Follow up Online Questionnaire Letter]	3.0	16 October 2018
Other [HORIZONS Notice About Data Protection Statement]	1.0	19 October 2018
Other [HORIZONS Online Questionnaire Partial Completion Letter]	1.0	20 August 2018
Other [HORIZONS Qualitative Reply Slip]	1.0	12 September 2018
Other [HORIZONS Online Questionnaire Nonresponse Reminder Letter]	1.0	20 August 2018
Other [HORIZONS Qualitative Sociogram Instructions]	1.0	09 January 2019
Other [HORIZONS Qualitative Sociogram Instructions - Tracked]	1.0	09 January 2019
Other [HORIZONS Qualitative Letter Introducing Sociogram]	1.0	09 January 2019
Other [HORIZONS Qualitative Letter Introducing Sociogram - Tracked]	1.0	09 January 2019
Other [HORIZONS Participant Contact Details Sheet]	3.0	08 January 2019
Other [HORIZONS Participant Contact Details Sheet - Tracked]	3.0	08 January 2019
Other [HORIZONS Your Answers Matter Postcard]	6.0	09 January 2019
Other [HORIZONS Your Answers Matter Postcard - Tracked]	6.0	09 January 2019
Other [HORIZONS Site Thank You Card]	1.0	09 January 2019
Other [HORIZONS Site Thank You Card - Tracked]	1.0	09 January 2019
Participant consent form [HORIZONS Full Consent Form - Tracked]	4.0	29 November 2018
Participant consent form [HORIZONS Full Consent Form]	4.0	29 November 2018
Participant consent form [HORIZONS Qualitative Consent Form]	1.0	12 September 2018
Participant information sheet (PIS) [HORIZONS Qualitative PIS - Tracked]	1.1	21 January 2019
Participant information sheet (PIS) [HORIZONS Qualitative PIS]	1.1	21 January 2019

Participant information sheet (PIS) [_HORIZONS PIS - Tracked]	3.0	30 November 2018
Participant information sheet (PIS) [HORIZONS PIS]	3.0	30 November 2018
Research protocol or project proposal [HORIZONS Protocol - Tracked Changes]	5.1	21 January 2019
Research protocol or project proposal [HORIZONS Protocol]	5.1	21 January 2019

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

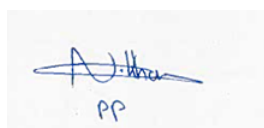
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

16/NW/0425:	Please quote this number on all correspondence
--------------------	---

Yours sincerely



On Behalf Of
Professor Karen Wright
Vice-Chair

E-mail: nrescommittee.northwest-preston@nhs.net

Enclosures: List of names and professions of members who took part in the review

North West - Preston Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 31 January 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh	Professor of Nursing	Yes	
Professor Karen L Wright (Vice-Chair)	Peel Trust Lecturer in Biomedicine	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Nafeesa Khanam	REC Assistant